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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,999	09/05/2003	Eric A. Schon	5199-23	8821

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EXAMINER
CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/655,999	SCHON ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-91* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to a method for introducing a functional peptide encoded by a plant or protist nucleic acid sequence into a mitochondrion of a mammalian cell by introducing a nucleic acid construct comprising a plant or protest nucleic acid encoding the peptide into a mammalian cell to produce a transformed cell, classified in classes 435 and 536, subclasses 455, and 23.6 and 23.7, respectively.

II. Claims 18-31, drawn to a method for correcting a phenotypic deficiency in a mammal that results from a mutation in a mitochondrial peptide by identifying the mitochondrial peptide having the mutation and introducing a nucleic acid construct comprising a plant or protist nucleic acid encoding the peptide into a mammalian cell to produce a transformed cell, classified in classes 514 and 536, subclasses 44, and 23.6 and 23.7, respectively.

III. Claims 32-41, drawn to a method for treating a mitochondrial disorder in a subject comprising administering to the subject a functional plant or protist peptide to treat said mitochondrial disorder, classified in class 514, subclass 2.

IV. Claims 42-47 and 67-71, drawn to a method for treating a mitochondrial disorder in a subject comprising administering to the subject a nucleic acid sequence encoding the functional plant or protist peptide to treat said mitochondrial disorder, and a pharmaceutical composition comprising said nucleic acid sequence, classified in classes 514 and 536, subclasses 44, and 23.6 and 23.7, respectively.

V. Claims 48-66, drawn to an expression vector for use in introducing a functional peptide encoded by an algal nucleic acid sequence into a mitochondrion of a mammal, comprising a nucleic acid sequence encoding *Chlamydomonas reinhardtii* ATPase 6 subunit of F0F1-ATP synthase or the mitochondrial-targeting signal thereof, and a mammalian cell transformed with said expression vector classified in classes 435 and 424, subclasses 320.1 and 93.2, respectively.

VI. Claims 72-91, drawn to a method for introducing a functional peptide into a mitochondrion comprising introducing a nucleic acid construct comprising a nucleic acid sequence encoding a peptide into a eukaryotic cell to produce a transformed cell, classified in classes 435 and 536, subclasses 455 and 23.1, respectively.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are a method for introducing a nucleic acid sequence encoding a functional plant or protist peptide into a mitochondrion of a mammalian cell vs. a method for correcting a phenotypic deficiency in a mammal that results from a mutation in a mitochondrial peptide. They are drawn to materially different methods that differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. They have different classifications and require separate search. There would be serious burden for examiner to search both groups. Thus, group I and group II are patentably distinct from each other. Similarly, group I and group

IV, group II and group VI, or group IV and group VI are patentably distinct from each other for the same reasons.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are a method for introducing a nucleic acid sequence encoding a functional plant or protist peptide into a mitochondrion of a mammalian cell vs. a method for treating a mitochondrial disorder in a subject comprising administering to the subject a functional plant or protist peptide. A nucleic acid sequence and a peptide differ in chemical structures, physical properties, and biological functions. They are drawn to materially different methods that differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. They have different classifications and require separate search. There would be serious burden for examiner to search both groups. Thus, group I and group III are patentably distinct from each other. Similarly, group III and group VI are patentably distinct from each other for the same reasons.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the expression vector of group V can be used as a probe for detecting the nucleic acid sequence encoding *Chlamydomonas reinhardtii* ATPase 6 subunit of F0F1-ATP synthase or for producing a recombinant protein in vitro as opposed to transform a

mammalian cell. Thus, group I and group V are patentably distinct from each other. Similarly, group V and group VI are patentably distinct from each other for the same reasons.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are a method for introducing a nucleic acid sequence encoding a functional plant or protist peptide into a mitochondrion of a mammalian cell vs. a method for introducing a nucleic acid sequence encoding a functional peptide into a eukaryotic cell. The nucleotide sequence and the target cell between groups I and VI are different. They are drawn to materially different methods that differ at least method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. They have different classifications and require separate search. There would be serious burden for examiner to search both groups. Thus, group I and group VI are patentably distinct from each other.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are a method for correcting a phenotypic deficiency in a mammal that results from a mutation in a mitochondrial peptide by using the recited nucleic acid construct vs. a method for treating a mitochondrial disorder in a subject comprising administering to the subject a functional plant or protist peptide. A nucleic acid sequence and a peptide differ in chemical structures, physical properties, and biological functions. They are drawn to materially different methods that differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response

variables, and criteria for success. They have different classifications and require separate search. There would be serious burden for examiner to search both groups. Thus, group II and group III are patentably distinct from each other. Similarly, group III and group IV are patentably distinct from each other for the same reasons.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are a method for correcting a phenotypic deficiency in a mammal that results from a mutation in a mitochondrial peptide by using the recited nucleic acid construct vs. a method for treating a mitochondrial disorder in a subject comprising administering to the subject a nucleic acid sequence encoding the functional plant or protist peptide. A method of correcting a phenotypic deficiency in a mammal that results from a mutation in a mitochondrial peptide and a method for treating a mitochondrial disorder in a subject are drawn to different scientific considerations. They have different designs and different mode of operations. They are drawn to materially different methods that differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. There would be serious burden for examiner to search both groups and they require separate search. Thus, group II and group IV are patentably distinct from each other.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP

§ 806.05(h). In the instant case the expression vector of group V can be used as a probe for detecting the nucleic acid sequence encoding *Chlamydomonas reinhardtii* ATPase 6 subunit of F0F1-ATP synthase or for producing a recombinant protein in vitro as opposed to correct a phenotypic deficiency in a mammal. Thus, group II and group V are patentably distinct from each other. Similarly, group IV and group V are patentably distinct from each other for the same reasons.

Inventions III and V are unrelated because the product of group V is not used or otherwise involved in the process of group III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER